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Antihomotoxic Treatment of Chronic Sinusitis

**Results of a Drug Monitoring Study with
Euphorbium compositum S Drops**

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Abstract

A total of 670 patients suffering from chronic sinusitis ($n = 390$), eustachian tubal catarrh ($n = 173$), middle-ear hydrops ($n = 39$) and other diseases ($n = 79$) were treated in a drug monitoring study with *Euphorbium compositum S* Drops as monotherapy or in combination with further medication. In 81% of the patients a first improvement of the symptoms was detectable during the first 2 weeks of treatment. During the first week, the rate of improvement was 60% with 35% after the first 3 days. The efficacy of the therapy was assessed by both investigators and patients as very good or good in more than 80% of the cases, irrespective of the use of additional medication. No deterioration was observed in any case. The tolerability of *Euphorbium compositum S* Drops was excellent or good for 97% of the patients.

Key words: Chronic sinusitis, eustachian tubal catarrh, middle-ear hydrops, drug monitoring study, *Euphorbium compositum S* Drops.

Introduction

The cause of chronic sinusitis is multifactorial. Inflammation of the paranasal sinus mucosa may derive from an infectious or non-infectious basis. Therefore the patients usually present with a broad pattern of long-term symptoms, local as well as general. Most frequent complaints include nasal obstruction, rhinorrhea and postnasal drip, associated with intermittent facial pain and general malaise (1, 2).

Current treatment objectives aim to reduce mucosal edema, to facilitate the drainage of sinus secretion, to maintain ostial permeability and to cure infection, if present (3). Accordingly, the conventional treatment of chronic sinusitis makes use of preparations for symptomatic relief, such as topical or systemic decongestants, inhalants, mucolytics and analgesics. In addition, antibiotics, corticosteroids and anti-inflammatory agents are routinely given for a certain period of time.

A different therapeutic approach is the basis of homeopathic treatment of chronic sinusitis. By stimulating regulatory processes, it is intended to modulate inflammation and thereby regenerate normal mucosal function. *Euphorbium compositum S* (manufactured by Biologische Heilmittel Heel GmbH, Baden-Baden, Germany) has been successfully used in the treatment of chronic sinusitis and other diseases of the upper respiratory tract for many years (4, 5). This preparation is available in the form of drops, injection solution and nasal spray, and in each dosage form contains eight single homeopathic remedies (*Euphorbium*, *Pulsatilla*, *Luffa operculata*, *Mercurius bijodatus*, *Mucosa nasalis suis*, *Hepar sulfuris*, *Argentum nitricum* and *Sinusitis*

nosode), specifically selected for the treatment of chronic sinusitis (maxillary sinus, frontal sinus and ethmoidal areas), eustachian tubal catarrh (eustachian salpingitis) and middle-ear hydrops.

The data of a prospective drug monitoring study undertaken recently in Germany with *Euphorbium compositum S* Drops are reported here. The study was intended to ascertain further data on the therapeutic potential of the homeopathic preparation in connection with the specific indication.

Methods

Patients with chronic sinusitis, eustachian tubal catarrh, middle-ear hydrops or other diagnosis (to be specified) were included in this drug monitoring study. The data collected by the investigators included demographic data, disease/diagnosis, duration, possible pre-treatment and intensity of the disease, dosage regimen, possible additional medications or other therapies and duration of the therapy.

For the assessment of efficacy the following parameters were evaluated:

- moment of first improvement of the symptoms
- assessment of the efficacy of the treatment by investigator and patient (scale: very good = no more complaints, good = significant improvement, moderate = slight improvement, without success = no change and deterioration)

Assessment variables for therapeutic tolerability were:

- determination of possible side effects
- assessment of tolerability by the investigator (scale: excellent, good, moderate, bad)

Moment of first improvement of the symptoms

Indications	After the first application	After 1-3 days	After 4-7 days	After 1-2 weeks	After 2-4 weeks	More than 4 weeks	No improvement	Termination of treatment
Chronic sinusitis n = 390	2.8	20.5	26.2	25.4	14.9	5.1	3.6	1.5
Eustachian tubal catarrh n = 173	8.1	45.7	26.0	14.5	3.5	1.1	1.1	0.0
Middle-ear hydrops n = 39	2.6	41.0	25.6	7.7	20.5	2.6	0.0	0.0
Other diagnosis n = 79	5.1	40.5	21.5	13.9	8.9	2.5	5.1	2.5
All patients n = 670	4.5	30.6	25.4	20.1	11.5	3.7	3.0	1.2

Table 1: Moment of first improvement of the symptoms. Percentage in the different indications and in the total patient population. Multiple assignment was possible.

Statistical analysis of the data was performed exploratively by calculating absolute and relative frequencies.

Results

Patients

In this drug monitoring study 670 patients (61% female) were treated with *Euphorbium compositum S* by 65 general practitioners, 18 ENT specialists, 4 pediatricians and 3 internists. Patients from all age groups were included with similar frequency, no specific age group was preferred. As indication for the treatment with *Euphorbium compositum S*, chronic sinusitis was diagnosed most frequently (57%), followed by eustachian tubal catarrh (25%), middle-ear hydrops (6%) and others (12%). In the case of chronic sinusitis, the investigators specified the localization of the disease as follows: maxillary sinus (45%), frontal sinus (35%), ethmoid bone (12%), sphenoid bone (4%), with no data available: (4%). The intensity of the complaints was 'moderate' in 53% of the cases. The intensity 'mild' was documented for 15% and 'severe' for 13% of the patients, respectively (no data available: 19%). The actual pre-duration of the disease was up to two weeks for half of the patient population. Longer periods were reported with descending frequency (multiple assignment was possible). In total, 51% of the patients had a pre-treatment before they started therapy with *Euphorbium compositum S*. The respective percentage was higher in the

patient population with chronic sinusitis as an underlying disease (65% pre-treated). Pre-treatment was primarily medical (71%). Drugs most frequently prescribed were antibiotics/anti-infectives, antitussives/expectorants and rhinologics.

Treatment

The generally recommended dosage (10 drops 3x daily) was prescribed to 70% of the patients, the acute disorder dosage (10 drops every 15 minutes) to 11%, and 19% received a combination of both dosages. In total 1/3 of the patients were treated with *Euphorbium compositum S* as monotherapy and 2/3 received additional treatment. This concomitant therapy was medical for 31%, physical for 30% and medical plus physical for 39% of the patients. As additional medical therapy mainly rhinologics, immunotherapeutics and antitussives/expectorants were taken. 77% of the patients had a treatment duration in the range of 1 week to 2 months. Less than 1 week was reported for 8%, 2-3 months for 10% and more than 3 months for 4% of the patients. In chronic sinusitis patients the most frequent treatment duration was 2-4 weeks. During treatment, the prescribed dosage was not changed in 86% of the cases. When a change was documented, it was a dose reduction, exclusively.

Efficacy parameters

The moment of the first improvement of the symptoms was determined as one of

the parameters to assess the efficacy of the therapy. The data revealed that in 81% of the patients a first improvement was detectable during the first 2 weeks of treatment. During the first week, the rate of improvement was 60% with 35% improvement after the first 3 days. Overall, it can be stated from the data that during 4 weeks of therapy 92% of the patients responded to the treatment by an improvement of the symptoms (Table 1).

The overall assessment of efficacy by means of a 5-point rating scale was ascertained as a further parameter. Four different assessments were evaluated. Investigators and patients gauged the efficacy of therapy including concomitant medication/physical therapy or monotherapy with *Euphorbium compositum S*, respectively. In each of the assessments the therapy was rated as very good or good in more than 80% of the cases. No deterioration was observed in any case (Figure 1).

Tolerability

Out of the 670 patients, 2 reports of adverse events were obtained. One patient had diarrhea for 2 days with moderate intensity. The symptoms disappeared without sequelae and the therapy did not need to be interrupted. A relationship to the homeopathic preparation was regarded as unlikely. A second patient terminated the therapy because of symptoms of sweating and coughing. A relationship to the treatment with *Euphorbium com-*

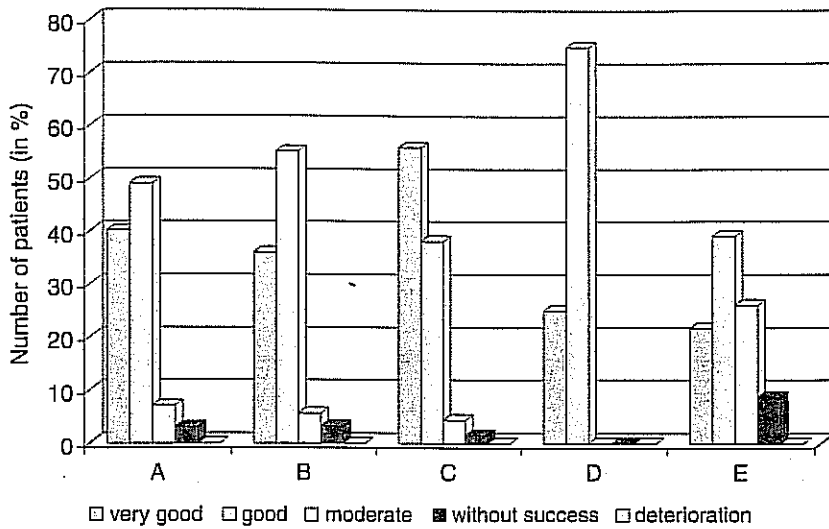


Figure 1: Investigators' global assessment of the efficacy of monotherapy with Euphorbium compositum S Drops in the total patient population and in the different indications. A = total patient population (n = 224), B = chronic sinusitis (n = 125), C = eustachian tubal catarrh (n = 68), D = middle-ear hydrops (n = 8), E = other diagnosis (n = 23). Multiple assignment was possible.

positum S was regarded as probable in the sense of a positive vicariation.

In general, the overall tolerability of treatment with Euphorbium compositum S was assessed by the investigators almost exclusively as excellent or good (97%).

Conclusion

This drug monitoring study was performed to obtain further data on therapeutic potential and tolerability of the homeopathic preparation Euphorbium compositum S in the treatment of chronic sinusitis and other diseases under routine care of general practitioners and other physicians. In view of the increasing gen-

eral toxic situation due to environmental stress and the rapidly growing incidence of chronic diseases, an antihomotoxic combination preparation seems to be a promising general therapeutic approach.

The patients treated in this investigation showed a fast and significant improvement in their disease status, documented by the moment of first improvement and the overall efficacy assessment of investigators and patients. These results were similar for monotherapy with Euphorbium compositum S and for therapy in combination with further medication. Positive effects on the reactivation of the mucosa can therefore be suggested as a

therapeutic approach. Beside the positive efficacy assessment, the tolerability of the medication was excellent or good in almost all of the cases.

It can be concluded that Euphorbium compositum S, which contains eight single homeopathic remedies, leads to a broad, in-depth therapeutic effect in the treatment of chronic sinusitis, eustachian tubal catarrh, middle-ear hydrops and other diseases, primarily of the upper respiratory tract.

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